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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,275	02/05/2002	Edward J. Petrus	EJP-2002-2	3053
. 75	90 07/27/2004		EXAMINER	
EDWARD J. PETRUS 3413 SPANISH OAK DR.			LEWIS, PATRICK T	
AUSTIN, TX 78731			ART UNIT	PAPER NUMBER
·			1623	
	•		DATE MAILED: 07/27/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
Office Action Summary		10/068,275	PETRUS, EDWARD J.		
		Examiner	Art Unit		
		Patrick T. Lewis	1623		
Period fo	The MAILING DATE of this communicat or Reply	ion appears on the cover sheet w	th the correspondence address		
THE - Exte after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICA nsions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communicate period for reply specified above is less than thirty (30) date period for reply is specified above, the maximum statutor reto reply within the set or extended period for reply will, be reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	TION.  CFR 1.136(a). In no event, however, may a ration.  ys, a reply within the statutory minimum of thin y period will apply and will expire SIX (6) MON by statute, cause the application to become AE	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).		
Status					
1)	Responsive to communication(s) filed or	n			
2a) <u></u>	This action is <b>FINAL</b> . 2b)	☑ This action is non-final.			
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposit	ion of Claims				
5)□ 6)⊠ 7)□	Claim(s) <u>1-13</u> is/are pending in the applied 4a) Of the above claim(s) is/are with Claim(s) is/are allowed.  Claim(s) <u>1-13</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction	vithdrawn from consideration.			
Applicati	ion Papers				
9)[	The specification is objected to by the Ex	kaminer.			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
	Applicant may not request that any objection	=			
11)□	Replacement drawing sheet(s) including the The oath or declaration is objected to by	•			
Priority (	ınder 35 U.S.C. § 119				
a)(	Acknowledgment is made of a claim for the All b) Some * c) None of:  1. Certified copies of the priority documents.  2. Certified copies of the priority documents.  3. Copies of the certified copies of the application from the International See the attached detailed Office action for	uments have been received. uments have been received in A ne priority documents have been Bureau (PCT Rule 17.2(a)).	pplication No received in this National Stage		
Attachmen	, ,				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-		summary (PTO-413) s)/Mail Date		
3) Infon	nation Disclosure Statement(s) (PTO-1449 or PTO r No(s)/Mail Date		nformal Patent Application (PTO-152)		

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## **DETAILED ACTION**

### Information Disclosure Statement

1. The disclosure does not contain references listed on a proper information disclosure statement. Therefore, unless the references have been cited by the examiner on form PTO-892, applicant should not assume references have been considered.

# **Double Patenting**

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 3. Claims 1-7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 6,346,519. This is a double patenting rejection.
- 4. Claims 8, 10, 11, and 13 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 4, and 6 of prior U.S. Patent No. 6,656,925. This is a double patenting rejection.

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7, 9, and 12 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,656,925. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-7 are drawn to a method for treating arthritis in mammals by administering a therapeutically effective amount of a composition comprising an inhibitor or nitric acid synthase and an aminosugar. Claim 2 limits the aminosugar in the composition. Claim 3 requires an additional agent. Claim 4 further requires that the composition has an enteric coating. Claim 5 further requires that the composition comprises a carrier. Claims 6-7 further limit the inhibitors of nitric oxide synthase. Claims 9 and 12 are drawn to a composition comprising an inhibitor of nitric oxide production and an amino sugar. Claim 9 further limits the inhibitors of nitric oxide production. Claim 12 reads upon a composition that optionally uses a controlled

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release method of enteric coating to deliver the composition orally into the gastrointestinal tract.

The instantly claimed method for treating arthritis in mammals differs from the method claimed in the '925 patent in that composition of the '925 patent employs an inhibitor of nitric oxide production compared to an inhibitor of nitric oxide synthase; however, there is substantial overlap in the inhibitors employed (both methods employ zinc compounds, arginine derivatives, redox dyes, L-canavarine, and methylene blue for example). Applicant should also note that there may be possible typographical errors in claims 2, 5, and 8 of the '925 patent. For example, claims 2 and 5 are drawn to "the method of claim 1"; however, claim 1 is drawn to a composition. A proper dependent claim incorporates all of the limitations of the independent claim. The examiner has been interpreted claims 2 and 5 to read upon "the composition of claim 1". Claim 8 has been interpreted to read upon "the method of claim 7".

### Conclusion

Claims 1-13 are pending. Claims 1-13 are rejected. No claims are allowed. 7.

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## Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD

Examiner Art Unit 1623